REMARKS

Application Status

In the July 25, 2005 Final Office Action, the Examiner restricted method claims 37-43 and withdrew them from consideration as being directed to a non-elected invention.

The Examiner rejected claims 27-36 as indefinite under 35 U.S.C. § 112, ¶ 2, because it was "unclear whether the Applicant is claiming the implant is made from apophyseal bone or the implant comprises cortical bone formed into a prosthetic apophyseal ring." (Examiner's emphasis).

The Examiner rejected Claim 29 under 35 U.S.C. § 112, ¶ 1 because there was no description in the specification of the limitation wherein "the associated support is adapted to be configured in different lengths." (Examiner's emphasis).

Claims 27 and 32-36 were rejected under § 103(a) as obvious over Boyd et al, U.S. Pat. No. 6,468,311.

Applicants have amended claims 27, 32, and 34. Claim 28 has been cancelled. Claims 27 and 29-36 are in the case. Applicants respectfully request reexamination and reconsideration of the claims.

Rejection Under 35 U.S.C. § 112, ¶ 2

Applicants have amended claim 27. Applicants submit, however, that the claim before amendment was sufficiently clear to one of ordinary skill in the art. In view of

Applicants' remarks below, they respectfully request reconsideration of the claims and withdrawal of the paragraph 2 rejection.

In Applicants' rejected claim 27, the allograft was claimed as "solid bone" that included an "apophyseal ring" which is typically made of "cortical bone." That language, taken in conjunction with the specification and Figures 4-8 of the application, demonstrates that each portion of the claimed allograft comprises original cadaveric vertebra with its own natural apophyseal ring comprised of cortical bone. As claim 27 was previously drafted, and as it is currently drafted, the anterior member and the two lateral members are solid, unitary portions of cadaveric vertebrae that retain their original apophyseal ring. Each member is suitable for implantation without substantial processing or alteration. If necessary, the only significant alteration to the original cadaveric bone should be sizing, trimming, and fitting, so that the patient's vertebrae can accommodate the placement of the allograft. The preferred embodiment of Applicants' invention is a single piece of cadaveric vertebrae that includes the anterior and lateral members, although more sizing, trimming, and fitting will be required if separate pieces are used for the anterior and lateral members.

In contrast to the present invention, the prior art used bone that was typically unsuitable for implantation by itself, whether the bone was harvested from a donor, a cadaver, or the patient. For example, Boyd et al, U.S. Patent No. 6,468,311, discussed below in response to the Examiner's obviousness rejection, states that "donor bone otherwise unsuitable for implantation may be used . . . ." Col. 6, lines 42-43.

In the rejection under 35 U.S.C. § 112, ¶ 2, the Examiner stated that it was "unclear whether the Applicant is claiming the implant is made from apophyseal bone or the implant comprises cortical bone formed into a prosthetic apophyseal ring." (Examiner's emphasis). Applicants respectfully submit that the language of claim 27, both before and after amendment, show that the present invention is neither. The purpose of the present invention is to reasonably approximate the shape and configuration of the adjacent vertebrae. The invention is not "made from" or created out of an apophyseal ring or cortical bone – it is original cadaveric bone that includes a significant portion of the original apophyseal ring of that cadaveric bone. Because the allograft of the present invention takes advantage of the apophyseal ring of a patient's vertebrae, the allograft itself should have corresponding strength at the same location. Using material that is shaped substantially like and functions substantially like the structure in the patient's body is a significant aspect of the present invention. When using bone as the material for the invention, Applicants have claimed that the cadaveric bone be like the patient bone adjacent to which the allograft will be placed – that it have the structural and functional equivalent of an apophyseal ring.

Applicants also note that they have rearranged some of the language of claim 27. While it may appear at first that Applicants have made significant changes to claim 27, much of the original claim language has simply been transposed. Applicants submit that the amendments were not made to overcome the Examiner's section 112 rejection and merely facilitate the reading of the claim. For ease of understanding the nature of the of

the changes to the claim, at the end of this paper Applicants' attorney has attached a copy of amended claim 27 without the deletions and additions shown on pages 2-3 above.

Similarly, Applicants have amended claims 32 and 34 by adding the word "adjacent" before "vertebral body." Before amendment, the term "the vertebral body" already possessed an antecedent basis, and one of ordinary skill understood that "the vertebral body" was the patient's vertebrae adjacent to the allograft. The purpose of the present claim revisions is not related to patentability and is not directed to one of ordinary skill in the art. The revisions organize the claims for those of less than ordinary skill in the art, such as a lay jury who would consider the claims during infringement litigation.

Applicants respectfully submit that the amendments to claim 27, which apply to dependent claims 29-36, simply restate the claimed subject matter in a different way than the original claim 27, but that either version can be understood by one of ordinary skill in the art. Therefore, Applicants respectfully request that the Examiner withdraw his rejection under 35 U.S.C. § 112, ¶ 2.

Rejection Under 35 U.S.C. § 112, ¶ 1

Applicants respectfully disagree with the Examiner's rejection of claim 29 under the written description requirement of paragraph 1. The "associated support" of claim 29 inherently can be "adapted to be configured in different lengths." At the present time, the associated support is preferably the prior art cages 20, such as those depicted in Figures 7-8 and described throughout the specification. The associated support should not, however, be specifically limited to cages. The "associated support" can be another

structure – made from bone, metal, or nonmetallic material – that performs substantially the same function as a cage. It is well-known in the art to vary the cage sizes to accommodate a patient's vertebrae size. Therefore, one of ordinary skill in the art would know to do so whether the associated support was a cage or another structure that performs substantially the same function as a cage.

Rejection Under 35 U.S.C. § 103

Claims 27 and 32-36 were rejected as obvious over Boyd. Applicants respectfully disagree. The present invention is configured to take advantage of both the patient's vertebral apophyseal rings and that of the cadaveric allograft, which has its own apophyseal ring. Boyd does not do so.

Applicants intend to file a continuation-in-part application on an allograft of a man-made material. To avoid waiving arguments as to the patentability of certain features of claim 27 that may appear in the CIP application, Applicants below present arguments concerning the patentability of original claim 27. However, to obtain allowable subject matter as quickly as possible, Applicants have amended claim 27 to include the limitation of now-cancelled claim 28. The Examiner did not reject claim 28 on any prior art basis, and Applicants respectfully submit that claim 27 as amended is now in condition for allowance. Since claims 29-36 all depend directly or indirectly from claim 27, Applicants respectfully submit that claims 27 and 29-36 are in condition for allowance.

The invention claimed in original claim 27 has been designed with a configuration so that the allograft provides support to the adjacent vertebrae at the apophyseal ring. The function and structure of the apophyseal ring was explained in Applicants' amendment mailed April 21, 2005. It is well-known that the apophyseal ring is capable of supporting higher loads than the softer, cancellous bone that makes up the remainder of a vertebral body. The present invention is designed to take advantage of its ability to provide support at the apophyseal ring to improve upon the devices commonly in use today, which typically encounter subsidence problems. Applicants also believe that implanting a structure similarly configured to the adjacent structure – in this case the vertebrae – may obtain additional clinical benefits that a structure like Boyd will not.

Boyd is neither configured like nor functions like the present invention. Boyd is not designed to make significant use of the support provided by the apophyseal ring of a patient's vertebrae. Boyd also relies on a larger supporting surface area of soft, cancellous bone, which may be helpful, but which may still be subject to subsidence. The present invention maintains the continuity of a patient's spine at the point of the allograft, thus maintaining the continuity and symmetry of forces along the spine. In contrast, the unnatural shape of Boyd does not perform this function. This distinction can be seen in Figure 9 of Boyd, where ends of the lateral members of Boyd are not configured to take advantage of the apophyseal ring of adjacent vertebrae. Boyd is one more modular device similar to others that have clinically failed with appreciable frequency. Many of those failures are attributable to either subsidence of the modular device, its complexity, or both.

It should be noted that even as amended, claim 27 is patentably distinct from Boyd. The allograft provides support for the patient's vertebrae primarily at the strongest and most mechanically symmetrical location, at the apophyseal ring. The "associated support" connected to the allograft provides secondary support and fusion in the area of the softer cancellous bone. In contrast, devices like Boyd provide more support in the area of the cancellous bone and on individual points of the apophyseal ring, thus realigning vertebral forces and creating a greater likelihood of subsidence.

That Boyd contemplates his implant may include portions made of bone does not render the present invention obvious. As described in the Abstract, Boyd's use of bone is only "to promote fusion of the vertebrae." Boyd contemplates "the use of bone segments otherwise unsuitable due to size or strength." Col. 6, lines 42-43. While the bone allograft of the present invention will promote fusion of the vertebrae, it is also patentably distinct from Boyd because Applicants' device does contemplate bone of suitable strength that is cut and sized for its specific application and for the strength advantages of its own apophyseal ring and that of adjacent vertebrae.

In view of the preceding comments, Applicants submit that Boyd does not render obvious either original or amended claim 27.

Conclusion

Applicants respectfully request reconsideration and reexamination of claims 27 and 29-36. In view of the amendments and the preceding remarks, a prompt notice of

allowance is earnestly solicited. If the Examiner has any comments or questions regarding this amendment, please telephone the undersigned.

Respectfully submitted,

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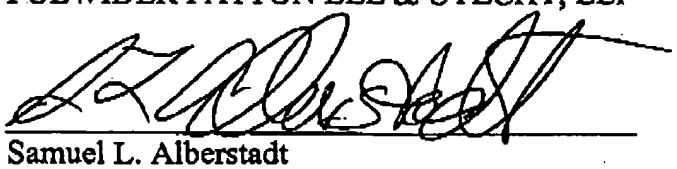
By: 

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